UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,521	12/21/2000	Darrel R. Galloway	22727/04079	9991

24024 7590 02/21/2007
CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/747,521	GALLOWAY ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26,27,31,41,42,45-49 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 26, 27, 31, 41, 42, 45-49 and 53-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2x2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The response filed 3-31-06 and the amendments to the specification and drawings filed 3-31-06 have been entered into the record. The amendment to the claims filed 5-1-06 has been entered into the record. Claims 24, 26, 27, 31, 41, 42, 45-49 and 53-57 are pending and under examination. Claims 1-23, 25, 28-30, 32-40, 43-44 and 50-52 have been cancelled.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Information Disclosure Statement

The information disclosure statements filed 3-31-06 and 7-06 have been considered. Initialed copies are enclosed.

Rejections Withdrawn

The objection to claims 46 and 48 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the amendments to the claims.

Claims 24, 26, 27, 31, 41, 42, 45-50, 53-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons made of record in the Office Action mailed 9-29-05. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record is withdrawn in view of the addition of the new matter to the specification..

Objections/Rejections Maintained

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 and 101 for claims 24, 26, 27, 31, 41, 42, 45-50 and 53-57 of this application as set forth below.

Claims 24, 26, 31, 42, 46, 48, 49, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (Vaccine, 1(4):340-344, Feb 1999; publicly available online January 4, 1999) in view of Brossier et al (Infection and Immunity, 68(4):1781-1786, April 2000), Little et al (Infection and Immunity, 52(2):509-512, 1986), Singh et al (Infection and Immunity 66(7):3447-48, July 1998), Park et al (Protein Expression and Purification, 18:293-302, April 2000) and Donnelly et al (Annu. Rev. Immunol, 15:617-48, 1997) is maintained in view of the insertion of new matter into the instant specification and as such, this application has been examined in view of the instant filing date as reflecting the addition of the new matter into the specification.

Claims 27, 41, 45, 47, 53 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (Vaccine, 1(4):340-344, Feb 1999; publicly available online January 4, 1999) in view of Brossier et al (Infection and Immunity, 68(4):1781-1786, April 2000), Little et al (Infection and Immunity, 52(2):509-512, 1986), Singh et al (Infection and Immunity 66(7):3447-48, July 1998), Park et al (Protein Expression and Purification, 18:293-302, April 2000) and Donnelly et al (Annu. Rev. Immunol, 15:617-48, 1997) as applied to claims 24, 26, 31, 42, 46, 48, 49, 53 and 54 above, further in view of Glorioso et al (US Patent No 5,998,174, issued December 7, 1999, filed May 12, 1997) is maintained in view of the insertion of new matter into the instant specification and as such, this application has been examined in view of the instant filing date as reflecting the addition of the new matter into the specification.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al (Vaccine, 1(4):340-344, Feb 1999; publicly available online January 4, 1999) in view of Brossier et al (Infection and Immunity, 68(4):1781-1786, April 2000), Little et al (Infection and Immunity, 52(2):509-512, 1986), Singh et al (Infection and Immunity 66(7):3447-48, July 1998), Park et al (Protein Expression and Purification, 18:293-302, April 2000) and Donnelly et al (Annu. Rev. Immunol, 15:617-48, 1997) as applied to claims 24, 26, 31, 42, 46, 48, 49, 53 and 54 above, further in view of Felgner et al (US Patent 6,710,035, issued March 23, 2004 with priority to March 21, 1990) is maintained in view of the insertion of new matter into the instant specification and as such, this application has been examined in view of the instant filing date as reflecting the addition of the new matter into the specification.

New Rejections Based on Amendment

The amendment filed 3-31-06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants now insert the phrase "the disclosure of which is hereby incorporated by reference in its entirety." It is noted that applicants rely upon this newly inserted incorporation by reference to insert Example 4 and new Figure 7 into the specification, residues 83-283 of SEQ ID NO:2. There is no statement of intent to incorporate the provisional document in the original priority claim to the provisional application or in any transmittal paper. Inclusion at this date and the insertion of the new material is deemed new matter. It is noted that 37 CFR 1.57(a) applies to applications filed on or after September 21, 2004. 37 CFR 1.57(a) permits inadvertently omitted material to be added to the application by way of a later filed amendment if the inadvertently omitted portion of the specification or drawing(s) is

completely contained in a prior-filed application (for which priority/benefit is claimed) even though there is no explicit incorporation by reference of the prior-filed application. It is noted that this application does not meet the criteria of 37 CFR 1.57(a). Further, residues 83-283 of SEQ ID NO:2 is not supported by the provisional document at pages 4-5 because the fragment described therein contain a specific mutation, where as residues 83-383 of SEQ ID NO:2 does not.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 24, 26, 27, 31, 41, 42, 45-50 and 53-55 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants' amendments to the claims rely upon the material that was inserted into the specification by amendment. This material is deemed new matter for the reasons set forth above.

Applicant is required to cancel the new matter in reply to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24, 26, 27, 31, 41, 42, 45-49 and 53-57 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

The claims are directed to a vaccine to protect against lethal *infection*. There is no existing vaccine that protects against *infection*. The existing vaccines provide for a preexisting immune response sufficient to combat initial infection without having sings or symptoms of the disease. The instantly claimed vaccine is directed to the two parts of the tripartite toxin (lethal factor and protective antigen) produced by *Bacillus anthracis*. The tripartite toxin is produced and secreted by the live microorganism in the host. The specification teaches that the vaccine neutralizes the toxin. In bacteriological infection, the toxin is not produced from the bacteria in a host, *absent the host being infected by the bacterium*. Therefore, the vaccine cannot protect from lethal infection, because the vaccine cannot protect from infection at all. The composition is limited in function to generation of toxin-neutralizing antibodies. These antibodies are present *in vivo* and have the capability to neutralize toxin produced by *Bacillus anthracis* infection. The teachings of the specification do not provide for lethal infection, nor would one expect that mere toxin antibodies would protect from lethal infection because the toxic and lethal activities of *Bacillus anthracis* is not limited to LF and PA toxin production. Applicant's declaration under 37 CFR 1.132 is not persuasive because it does not demonstrate protection from infection *per se*. In fact, the animals were deliberately given 50 times the LD_{50} of *B. anthracis* endospores such that they became infected. It is noted that bacterial endospores are a dormant body which *Bacillus anthracis* can develop within them under conditions of stress (like lack of nutrients), which is highly resistant to harsh environmental conditions and which can develop into a new, live bacterium once conditions are good again. Bacterial endospores do not produce toxin, they are dormant. Therefore, the spores must germinate into a vegetative bacterium in order to produce the tripartate toxin. The fact that the spores germinate in the host and produce toxin that can be neutralized by antibodies, indicates that infection has occurred. Therefore, the vaccine cannot protect from lethal or any infection because the animals become infected.

Status of Claims

Claims 24, 26, 27, 31, 41, 42, 45-49 and 53-57 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645